

REPORT TO CONGRESS

MEDICAID DRUG USE REVIEW DEMONSTRATION PROJECTS

Donna E. Shalala
Secretary of Health and Human Services
1994

Table of Contents

CHAPTER 1	
BACKGROUND OF THE DEMONSTRATIONS	1
Drug Use Review and Pharmacists' Cognitive Services	1
OBRA 1990 and Medicaid Drug Use Review Demonstrations	2
 CHAPTER 2	
PROGRESS TO DATE IN THE IOWA AND WASHINGTON DEMONSTRATIONS	4
Progress in Iowa's OPDUR Demonstration	4
Demonstration Design	4
The OPDUR Demonstration Intervention	4
Iowa's Research Hypotheses	5
Progress in Washington's Cognitive Services Demonstration	6
Washington's Demonstration Design	6
The Cognitive Services Demonstration Intervention	6
Washington's Research Hypotheses	7
Progress in the Demonstration Evaluation	7
 CHAPTER 3	
DEMONSTRATION EVALUATION PLANS	10

CHAPTER 1

BACKGROUND OF THE DEMONSTRATIONS

Section 1927 (g) of the Social Security Act, as added by section 4401(a)(3) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), requires that all State Medicaid programs implement both retrospective and prospective drug use review and pharmacist counseling programs. Section 4401(c) of OBRA 1990 also calls for demonstrations to test the effectiveness of two specific interventions relative to prescription drugs:

- 1) implementation of a system of on-line prospective drug use review (OPDUR) in at least 10 States, and
- 2) reimbursement of pharmacists' cognitive services for no fewer than 5 States.

The Health Care Financing Administration (HCFA) sent requests for proposals to all 50 States. Only 5 States responded to our solicitation: California, Florida, Iowa, Mississippi and Washington. An expert panel recommended that HCFA fund the Iowa and Washington demonstration projects. HHS submits this initial Report to Congress on the status of these demonstrations.

Drug Use Review and Pharmacists' Cognitive Services

In recent years, drug prescription and dispensing practice has evolved away from a model in which physicians prescribe and pharmacists dispense toward one in which pharmacists take a more active role in counseling patients and conferring with prescribers on medications.

One tool pharmacists and program administrators may use to inform such interactions is drug use review (DUR), a process of using screens based on clinically-relevant criteria to identify potential prescribing problems. DUR may be retrospective with a centrally-administered system that uses profiles to characterize past performance of prescribers, drug classes, or classes of patients against predetermined criteria. DUR may also be prospective by supplying information to the pharmacist at the time a patient presents a prescription (at the "point of sale"). Prospective DUR may be based on information stored at the pharmacy (on-site) or available through a central data base (on-line DUR). The pharmacist combines his or her own professional expertise and knowledge of the patient with DUR information to decide what action (if any) to take in order to prevent potential prescription problems (e.g. incorrect dosage, therapeutic duplication, and drug/allergy interactions).

On-line prospective DUR provides all pharmacists with rapid access both to standardized drug screens and to centrally-maintained information on patients' prescription histories, regardless of where

the drugs were purchased. In contrast, on-site prospective DUR screening criteria and software often differs among pharmacies, and each pharmacist has access only to histories of prescriptions sold at that specific facility.

Cognitive services are formally defined as "...services provided by a pharmacist to or for a patient or health care professional that are either judgmental or educational in nature rather than technical or informational."¹ When pharmacists take action to correct what appear to be prescription problems, they are providing cognitive services.

Proponents of DUR and cognitive services assert that pharmacist interventions, by lowering the incidence of inappropriate prescribing, will reduce both the costs of medications and the risks of adverse health outcomes. Research on these issues is inconclusive. Jay et al.² reviewed evaluations of State Medicaid retrospective DUR programs and found that they suffer from poor study design, inadequate data quality, and reliance on anecdotal evidence. Jay's own evaluation of California's Therapeutic retrospective DUR program showed no measurable effect of DUR on health outcomes. Large-scale research on payment for cognitive services has been limited by the fact that no Medicaid programs have paid for cognitive services, and the practice is not common among private payers. There has been no research into the effectiveness of on-line prospective DUR.

OBRA 1990 and the Medicaid Drug Use Review Demonstrations

Before 1993, all State Medicaid programs were required to conduct surveillance to detect prescription fraud and abuse through the Surveillance Utilization Review (SUR). Only 17 States used retrospective DUR for general educational purposes and to improve prescribing among providers that serve Medicaid recipients. Some States have begun to implement on-line prospective DUR. For example, Missouri, Maryland, West Virginia, and Texas, among others, already have on-line prospective DUR programs in place. All State Medicaid programs are required to implement on-site prospective DUR in response to OBRA 1990 mandates. According to a recent HCFA survey, at least 19 States currently have plans to integrate on-line prospective DUR with electronic claims management (ECM), a system that allows pharmacists to bill Medicaid electronically, over the next 3 to 4 years.

¹ American Pharmacy. Working group bibliography: payment for cognitive services: the future of the profession. 1989;NS29:768. cited in Christensen, D. B. Waiver Cost Estimate: State of Washington Cognitive Services Demonstration Project. Draft 2, June 6, 1993.

² Jay, E.D.; Eynon, B.P; Javitz, H.S. The Medi-Cal Therapeutic Drug Utilization Review Project: Quarterly Report and Final Analysis Report. Prepared by SRI International under subcontract to the Virginia Computer Company. Menlo Park, CA. July 1991

Demonstrations of cognitive services and on-line prospective DUR will be implemented to test the hypothesis that these enhancements would be cost-effective, would promote improved prescribing practices, and would reduce adverse health outcomes related to misprescribing, when combined with the basic retrospective DUR and counseling requirements of OBRA 1990. Since previous research provides no firm evidence for or against these hypotheses, the demonstrations and their evaluations will produce the first body of data capable of supporting such analyses.

As authorized by OBRA 1990, HCFA awarded cooperative agreements to two Medicaid programs to test specific interventions.

Iowa. The Iowa Department of Human Resources, in cooperation with researchers from the University of Iowa, Drake University, and the Iowa Pharmacists Association, were awarded a cooperative agreement in October 1992 for a demonstration project to develop, implement, and test programs for on-line prospective DUR for prescription medications dispensed to Medicaid recipients. Iowa will develop and test the system over a 15-month period, followed by a 3-year operational phase. Analyses and evaluation of the results will be completed in the last operational year.

Washington. The Washington Department of Social and Human Services, with the University of Washington School of Pharmacy, was awarded a cooperative agreement in October 1992 to design, implement and test a demonstration project in which pharmacists' cognitive services provided during the dispensing of prescription medications to Medicaid recipients are reimbursed. Washington will devote the first year to design and development of the project. Reimbursement and documentation of cognitive services will be in effect for only one year. Washington will complete analysis and evaluation activities in the third year of the project.

In March 1993, HCFA awarded a contract to Abt Associates, Inc., for an evaluation of the demonstrations.

CHAPTER 2

PROGRESS TO DATE IN THE IOWA AND WASHINGTON DEMONSTRATIONS

Since October 1992, demonstration staff in both the Iowa and Washington demonstrations have been planning for project implementation in 1994. They have refined preliminary demonstration designs, developed sampling plans for selecting participating pharmacies, begun to recruit pharmacies, and designed or negotiated for computer systems to support prescription screening and pharmacy reporting under the demonstration. Since March 1993, HCFA's evaluation contractor has been designing a study to evaluate the demonstrations.

Progress in Iowa's On-line Prospective DUR Demonstration

Demonstration Design. Iowa has defined geographic clusters for sampling pharmacies to participate in the demonstration. Project staff are recruiting pharmacies in contiguous metropolitan counties, located in two areas of the State. One area will be designated as the "treatment" area, within which participating pharmacies will receive the full on-line prospective DUR intervention. Pharmacies in the "control" area will not receive the intervention. These areas will be separated by a geographic corridor. This separation is expected to minimize border-crossing and spill-over effects that might contaminate the design, if prescribers or recipients were to use both treatment and control pharmacies. Iowa expects to recruit 100 treatment and 100 control pharmacies.

The On-line Prospective DUR Demonstration Intervention. Iowa's DUR program will allow pharmacists in the treatment area to review prescribed drugs at the point-of-sale. Treatment pharmacies will be linked to an on-line system for providing prospective DUR information integrated with point-of-sale ECM, and will receive feedback on drug screen failures from this system. Pharmacies in the control area will also be linked to the DUR information system, but will not receive any screening feedback. However, the Iowa research team will periodically monitor the screens that would have occurred in the control pharmacies and analyze claims data for hospitalizations and emergency room visits to determine if there may be a potential link to the recipient's drug therapy. If it is determined that there is a significant difference between the treatment and control group, the Iowa Department of Human Resources would stop the demonstration and provide on-line prospective drug utilization review throughout the State. In preparation for this demonstration, Iowa staff have been assessing the computer capabilities of Iowa pharmacies.

Iowa has awarded a contract to the National Data Corporation (NDC) to adapt its software to demonstration requirements and make it compatible with the Medicaid Management Information System used

by Paramax, Iowa's fiscal agent. Demonstration staff have been negotiating with NDC on the terms of this agreement. Paramax will serve as the host for the on-line prospective DUR software, providing at least two telecommunication switches for participating pharmacy access.

Iowa's on-line prospective DUR screens are in development. NDC will tailor an existing commercially available DUR system product for this demonstration. While this software includes a set of clinical modules that address a set of common problems, such as drug interactions and duplicative drug therapy, the thresholds for screen failures and the specific drugs to be included in the system will be set by the demonstration. In addition to the four screening criteria specified in the criteria developed by the University of Maryland and the Philadelphia College of Pharmacy and Science (dosage, duration of therapy, drug-drug therapeutic duplication, and drug-drug interaction), Iowa has been developing criteria for two other categories: drug allergy and drug-disease precautions. Iowa plans to validate the on-line prospective DUR computerized screening criteria over several months (October 1993 through February 1994).

To facilitate data collection on how pharmacists respond to the on-line prospective DUR screens, Iowa demonstration staff have expressed interest in adapting software that the Washington demonstration proposes to use for recording pharmacists' cognitive services. This software will allow pharmacists to enter coded descriptions of what actions they took, if any, when informed through DUR that a prescription failed a screen.

Iowa's Research Hypotheses. Project researchers have proposed to test several hypotheses using data from the on-line prospective DUR demonstration, including:

H(1) Pharmacies using on-line prospective DUR will have a lower percentage of screen failures than will control pharmacies.

H(2) Pharmacies using on-line prospective DUR will have a higher percentage of screen failures that result in drug therapy interventions than will control pharmacies.

H(3) Patients receiving care from pharmacies using on-line prospective DUR will have lower utilization and costs of all medical services, including prescription drugs, than will patients receiving care from control pharmacies.

H(4) There will be no difference in hospital admissions for adverse drug reactions for patients receiving care from pharmacies using on-line prospective DUR than patients receiving care from control pharmacies.

Progress in Washington's Cognitive Services Demonstration

Washington's Demonstration Design. Washington plans to define clusters, for the purposes of sampling treatment and control pharmacies, based on actual prescriber use patterns. Washington staff have designed a computer program that is being used to help researchers define a sampling frame. This sampling frame will assure that prescribers whose patients use pharmacies in treatment clusters do not also have patients who use pharmacies in control clusters. The sampling design will be independently evaluated by Abt Associates, Inc.

Demonstration staff in Washington propose to recruit 100 treatment and 100 control pharmacies. Treatment pharmacies will receive Medicaid payments for specific cognitive services. In addition, both treatment (Group A) and control (Group B) pharmacies will be provided a monthly flat payment for participating (and documenting the nature of cognitive services provided). A third "comparison" group of 100 pharmacies (Group C) will be identified but not recruited. These pharmacies will receive neither reimbursement nor a participation payment; they will provide data that will help researchers understand possible biases in the data from demonstration pharmacies, and will only be analyzed through secondary data (Medicaid claims).

The Cognitive Services Demonstration Intervention. Washington will reimburse pharmacists assigned to the treatment group for providing cognitive services that can be linked to a prescription problem and that involve a change in prescription, a decision not to dispense, or extended patient counseling. Pharmacists will receive \$4.00 for a brief intervention of 6 minutes or less, and \$6.00 for an extended intervention of over 6 minutes. Treatment and control pharmacies will each receive a flat monthly payment of \$40 to encourage them to document the cognitive services they provide. Throughout the planning year, demonstration staff from the University of Washington have worked to develop software that will allow pharmacists to enter coded information on what "cognitive services" they provided to correct problem prescriptions.

A critical component of the Washington demonstration is defining the scope of cognitive services and eligibility for reimbursement. The original plan included 17 drug problem codes, 7 intervention activity codes, and 8 prescription outcome codes. During 1993, staff from the University of Washington, in consultation with a panel of pharmacists, have been assessing these categories of cognitive services provided by pharmacists in order to determine whether or not they can be defined accurately for valid documentation. HCFA has final approval of the cognitive service categories that are reimbursed.

Washington's Research Hypotheses. Washington researchers propose to test the following hypotheses:

H(1) Cognitive services reimbursement will significantly increase the number of drug-related problems detected and, in turn, increase the number of interventions pharmacists perform to correct or resolve drug-related problems.

H(2) Reimbursing pharmacists for cognitive services will be cost-effective in reducing the cost of drug therapy.

Progress in the Demonstration Evaluation

As HCFA's evaluation contractor, Abt Associates, Inc. has responsibility for providing HCFA with generalizable findings on the impacts of retrospective and prospective DUR and payment for cognitive services. Data from the two demonstration States and information on Medicaid DUR activities from other States will form the basis of the evaluation findings. Specifically, the evaluation contractor has several objectives:

- working with each demonstration to coordinate the development of waiver cost estimates -- a draft waiver cost estimate has been completed and sent to HCFA for review;
- working with each demonstration to coordinate data collection and evaluation activities;
- working with each demonstration to design a minimum data set for the evaluation -- Abt's data processing staff have presented a list of data requirements to both demonstrations;
- monitoring the demonstrations' design and implementation activities;
- monitoring the implementation of retrospective and prospective DUR (on-line and on-site) in other States;
- obtaining and analyzing evaluation data, including Medicaid and Medicare eligibility and claims records, DUR and cognitive services program data, and data from surveys of prescribers and pharmacists, to address all research questions of interest to Congress.

To assist in implementing and evaluating the demonstration, HCFA convened two groups, each of which will meet throughout the project:

- A Technical Assistance Group (TAG), which will advise HCFA and the evaluation contractor on evaluation design

methodologies, research design, and interpretation of research findings. Ten experts have been recruited to the TAG, including health services researchers, pharmacoepidemiologists, clinical pharmacists, health economics researchers, and experts in pharmacology, pharmacy administration, the pharmaceutical industry, and DUR administration and policy. The first TAG meeting was convened on June 21, 1993. A followup meeting was held in January 1994.

- A State Liaison Committee (SLC), includes the Principal Investigator from each demonstration and, when appropriate, State Medicaid officials and other senior demonstration staff. The SLC will share information and comment on the development, implementation, and evaluation of the demonstrations and OBRA 1990 programs. The first SLC meeting was held on April 20, 1993.

The evaluation will include several components:

- construction and analysis of Medicaid prescription drug payment trend files for the two demonstration States, from 1989 through the period of the demonstration -- Abt has explored the options of using data from either the Medicaid Statistical Information System or requesting Medicaid data directly from the demonstration States, concluding that the latter is the preferred option; Abt's subcontractor, JEN Associates, has requested Medicaid data for the baseline period (1989 through 1993) from both Iowa and Washington;
- development of baseline evidence on the frequencies of drug problems in the demonstration States, using a consistent screening system; Abt's subcontractor, the Pennsylvania State University, has been designing a screening system for this purpose;
- construction and analysis of data files to describe Medicaid drug and other health services utilization and payment which, together with Medicare claims data and information on drug screen failures, will be used to test the effects of on-line prospective DUR and cognitive services on drug problems, drug use and costs, other health services use and costs, and access to services;
- surveys of Medicaid drug prescribers and pharmacists in the demonstration States, to assess changes in behavior related to the demonstration interventions -- draft instruments have been developed for these surveys;

- an annual national survey of all State Medicaid DUR programs, to monitor progress in implementing the OBRA 1990 DUR requirements;
- process analyses, based on site visits and regular monitoring of demonstration progress, to describe qualitative factors specific to Iowa and Washington that affect the ability of each demonstration to achieve its objectives;
- estimates of the cost-effectiveness of DUR and payment for cognitive services, through simulations that make use of data collected from the demonstrations.

CHAPTER 3

DEMONSTRATION AND EVALUATION PLANS

Both States plan to implement their demonstrations early in calendar year 1994. This will be the first of three demonstration years for Iowa. Washington's demonstration will run for one year. After the demonstrations have been phased out, staff in both States plan to conduct evaluations of their own.

HCFA's evaluation design will be revised by Abt staff and reviewed by the Technical Assistance Group, in preparation for analysis of baseline data from the demonstration States. The first Annual Report from the evaluation will be submitted to HCFA in May 1994. This report will review the experience of Iowa and Washington during the planning year and will present baseline statistics on trends in Medicaid drug expenditures and utilization in the demonstration States between 1989 and 1993. Using the consistent screener developed by Penn State, Abt will also report estimates of the baseline prevalence of potential prescription drug problems. After the demonstrations have been in operation for about one year, Abt will conduct the first of two site visits to the demonstrations, to document the implementation process. At about the same time, Abt will conduct the first of two waves of surveys designed to describe the behavior of prescribers and pharmacists during the demonstrations.

HHS will submit an additional Report to Congress on progress of these demonstrations approximately 12 months after the release of this report.

CMS LIBRARY



3 8095 00006074 5